

from the group consisting of a potyvirus, a tobamovirus, and a bromovirus.

56. (New) The method according to Claim 45, wherein said phenotypic changes are changes in growth rates, morphology, or color. -- .

In the Drawings

Figure 3, change "TTC" to --TCC--.

REMARKS

The Amendments

Claims 1-44 are canceled without prejudice as being drawn to non-elected invention.

Claim 45 is amended to clarify the meaning of the claim. Support for the amendments can be found, for example, in Claims 33-35 as filed.

New dependent Claims 46-56 are added. Support for the amendments can be found, for example, in Claims 10,11, 16-21, 24, 25 and 27 as filed.

Figure 3 is amended to change "TTC" to "TCC." "TCC" is a standard genetic code for the corresponding amino acid "Ser." "TTC" is a typographical error, which does not code for "Ser." Thus, this amendment is to correct an error and is supported by the standard genetic code for serine. A substitute sheet of Figure 3 and a sketch in red ink showing the proposed change are submitted herewith.

No new matter is added in any of the above amendment and the Examiner is respectfully requested to enter the amendments and reconsider the application.

The Remarks

Sequence listing requirement.

A new paper copy and computer readable format of sequence listing that comply with the requirements of 37 CFR 1.821 - 1.825 are enclosed herewith.

1. Restriction/election.

Applicants hereby confirm the election of claim 45 for prosecution. Claims 1 - 44 are cancelled without prejudice as being drawn to a non-elected invention.

2. Double patenting

Claim 45 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 43 of copending Application No. 09/359,297. Claim 45 is also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 45 of copending Application No. 09/359,305. Applicants will postpone addressing those provisional double-patenting rejections until Claim 45 becomes otherwise allowable.

3. 35 U.S.C. § 112, second paragraph rejection.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is traversed in view of the amendments.

The Examiner states that Claim 45 is vague and indefinite in that the metes and bounds of the phrase "...being in a positive sense orientation" are unclear. Applicants have amended the claim to recite the step that "transiently expressing said nucleic acid in a positive sense orientation in said growing plant host." The nucleic acid is transcribed in the cytoplasm to an RNA molecule substantially homologous to at least a portion of a mRNA being translated (see Positive-Sense definition at page 37). Therefore, Claim 45 is clear regarding "positive sense orientation."

The Examiner states that Claim 45 is vague and indefinite because the metes and bounds of the term "functional gene profile" are unclear. The Examiner suggests that it would be remedial to amend the claim language to clearly indicate how many of the possible genes from a donor or host organism associated with the determined biochemical or phenotypic change need to be identified in order to satisfy the limitation of being a "profile." Applicants have amended the claim to recite that repeating steps b) - f) until at least one gene from said donor organism or said plant host is identified, whereby a

positive sense functional gene profile of said plant host or said donor organism is compiled. Therefore, Claim 45 is clear regarding "functional gene profile."

The Examiner also states that Claim 45 is vague and indefinite in that it is unclear whether the functional gene profile necessarily includes identified genes associated with more than one trait associated with a biochemical or phenotypic change, or is necessarily limited to the identified genes associated with just one trait associated with a biochemical or phenotypic change. Applicants have amended the claim to recite that identifying a trait associate with a phenotypic or biochemical change. Therefore, a functional gene profile in Claim 45 is identifying a trait associated with a biochemical or phenotypic change.

The Examiner states that Claim 45 is vague and indefinite in that there is no explicit linkage between the vector of step (b) and the vector library of step (a). Applicants have amended the claim to recite constructing recombinant viral nucleic acids in step (a) and infecting a plant host with one of said recombinant viral nucleic acids in step (b). Therefore, the rejection is overcome in view of the amendments.

The Examiner states that Claim 45 is vague and indefinite in that the metes and bounds of the phrase "...identifying an associated trait where a phenotypic or biochemical change occurs..." are unclear. Applicants have amended the claim to recite "identifying a trait associated with a phenotypic or biochemical change," therefore, the rejection should be withdrawn.

The Examiner states that Claim 45 is vague and indefinite in that the metes and bounds of the phrase "...associated with the trait..." are unclear. The Examiner questions that how directly the host or donor gene has to be linked to the trait which is itself associated with the observed biochemical or phenotypic change. In Merriam Webster's Collegiate Dictionary, "associate" is defined as to bring together or into relationship in any of various intangible ways. After a host is infected with a recombinant viral nucleic acid comprising a nucleic acid insert derived from a library of cDNAs, genomic DNAs, or a pool of RNAs, one or more biochemical or phenotypic change is determined. A gene that has a relationship with a biochemical or phenotypical change, directly or indirectly, is associated with the trait that is itself associated with the change. Applicants believe

that the meaning "associated with the trait" is clear and respectfully request the Examiner to withdraw the rejection.

The Examiner rejects Claim 45 for being vague and indefinite in that it is unclear whether steps (f) and (g) are optional or required steps in the claimed methods. Applicants have amended the claim to combine steps (f) and (g) and recite that "identifying a donor gene or a plant host gene." Applicants have also amended the claim to recite that "whereby a positive sense functional gene profile of said plant host or said donor organism is compiled." Therefore, this specific rejection should also be withdrawn.

4. 35 U.S.C. §112 first paragraph rejection.

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of compiling a functional gene profile or an organism in which the vector library comprises inserts derived from known coding sequences (i.e. cDNAs or mRNAs) or their complementary sequences, does not reasonably provide enablement for such a method in which the vector libraries are derived from sources comprising non-coding sequences (e.g. gDNA, random synthetic sequences, etc.). This rejection is traversed because Applicants have amended the claim to recite "preparing a library of cDNAs, genomic DNAs, or a pool of RNAs from a non-plant donor organism."

The Examiner states that Claim 45 encompasses any nucleic acid such as genomic DNA which comprises sequences which are not part of, or complementary to, a coding sequence; there is no limitation as to the size of the insert DNA, meaning that any sized fragment from any source can be used to construct the library. The Examiner's statements are respectfully traversed. At page 20, line 23, through page 21, line 27, Applicants teach how to prepare a DNA insert comprising a nucleic acid sequence of a non-plant donor organism. Applicants describe how to prepare a library from cDNAs, genomic DNAs, or a pool of RNAs of an organism. The cDNAs, genomic DNAs, or a pool of RNAs are mechanically sized-fractionated or digested by an enzyme to smaller fragments. The fragments are ligated and cloned into recombinant viral nucleic acid

vectors. Recombinant plant viral nucleic acids containing a nucleic acid sequence insert are constructed using conventional techniques, which are exemplified by Examples 2, 4, 5, 11 and 19. Therefore, the Examiner's rejection should be withdrawn.

The Examiner states that the specification provides no guidance on how to construct a vector library in which all of the sequences are oriented in the vector in the same way. The Examiners' rejection is overcome in view of the amendments. Claim 45 is amended to recite that the recombinant viral nucleic acid is transiently expressed in a positive sense orientation in the grown plant host. At page 37, lines 1-3, Applicants define positive-sense orientation as a type of gene regulation due to the presence in a cell of an RNA molecule substantially homologous to at least a portion of the mRNA being translated. At page 21, lines 21-27, Applicants teach that the nucleic acid sequence of the recombinant viral nucleic acid is transcribed as RNA in a host plant; the RNA is capable of regulating the expression of a phenotypic trait by a plus sense mechanism. Alternatively, the nucleic acid sequence in the recombinant plant viral nucleic acid may be transcribed and translated in the plant host to change a phenotypic trait. In the specification, Applicants teach how to prepare a library of cDNAs, genomic DNAs, or a pool of RNAs and construct recombinant viral nucleic acids comprising a nucleic acid derived from the library. After a host is infected with a recombinant viral nucleic acid comprising a nucleic acid insert derived from a library of cDNAs, genomic DNAs, or a pool of RNAs; one or more biochemical or phenotypic changes in a host plant is determined.

The specification teaches different methods to determine phenotypic or biochemical change in a plant (see page 24, line 22 through page 26, line 13). The specification also teaches methods of determining the sequence of a nucleic acid insert and the sequence of an entire open reading frame of a gene (see page 29, lines 15-23). Once the nucleic acid sequence is determined, the orientation of the nucleic acid inserted is known. Therefore, the specification teaches a method of compiling the genes of a plant that code for a biochemical or phenotypic trait.

For the reasons stated above, the § 112, first paragraph rejection of Claim 45 should be withdrawn.

5. 35 U.S.C. §103(a) rejection.

Claim 45 is rejected under §103(a) as being unpatentable over Peterson *et al.* The rejection is traversed because Peterson *et al.* does not teach or suggest (a) constructing recombinant viral nucleic acids, and (b) transiently expressing the nucleic acids.

Peterson *et al.* disclose a method for making a mobilizable combinatorial gene expression library, comprising ligating a shuttle vector that replicates in different species or strains of host cells, to one or more cDNA or genomic DNA fragments to form a pool of expression constructs, wherein the genes contained in the cDNA or genomic DNA fragments are each operably-associated with their native or exogenous regulatory regions which drive expression of the genes in an appropriate host cell.

Peterson *et al.* describe a method for producing metabolic pathways in organisms using DNA derived expression libraries. However, Peterson *et al.* do not teach or suggest a method of constructing recombinant viral nucleic acids and using a viral vector.

Furthermore, the method of transiently expressing the nucleic acid in a positive sense orientation in the growing plant host is not taught or suggested by Peterson *et al.*

All of the constructs for plants described by Peterson *et al.*, refer to transformation of plants (i.e. transgenics). There is no teaching or suggestion as to transient expression vectors or RNA based replicons.

Many proteins cannot be constitutively expressed in transgenic systems because that would be lethal to host plants; but such proteins can be expressed in transient systems. For example, regulatory proteins such as transacting factors and metabolic enzymes have been expressed in whole plants using viral vectors. The same proteins are often difficult to be produced in transgenic plants because that would lead to cell death when the proteins are expressed at inappropriate times or locations during early development.

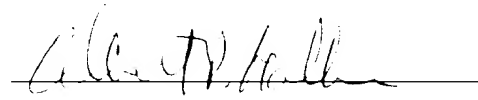
Also, Peterson *et al.* do not teach or suggest a method of compiling a plant positive sense functional gene profile. Therefore, the § 103(a) rejection of Claim 45 over Peterson *et al.* should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, the Applicants believe the application is in good and proper condition for allowance. Early notification of allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 463-8109. A telephone conference is especially requested if the Examiner intends to maintain the present rejections.

Respectfully submitted,

Date: September 26, 2000

A handwritten signature in dark ink, appearing to read "Albert P. Halluin", is written over a horizontal line.

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